

2005 DRAFTING REQUEST

Bill

Received: **06/17/2005**

Received By: **csundber**

Wanted: **As time permits**

Identical to LRB:

For: **Luther Olsen (608) 266-0751**

By/Representing: **Rebecca Hogan**

This file may be shown to any legislator: **NO**

Drafter: **phurley**

May Contact:

Addl. Drafters:

Subject: **Occupational Reg. - prof lic**

Extra Copies:

Submit via email: **YES**

Requester's email: **Sen.Olsen@legis.state.wi.us**

Carbon copy (CC:) to:

Pre Topic:

No specific pre topic given

Topic:

Pharmacy board emergency variance authority

Instructions:

See Attached

Drafting History:

<u>Vers.</u>	<u>Drafted</u>	<u>Reviewed</u>	<u>Typed</u>	<u>Proofed</u>	<u>Submitted</u>	<u>Jacketed</u>	<u>Required</u>
/?	csundber 06/27/2005			_____			
/1	phurley 06/27/2005	chanaman 07/25/2005	rschluet 07/26/2005	_____	Inorthro 07/26/2005		
	phurley 08/29/2005	kfollett 09/27/2005		_____			
/2			rschluet 09/27/2005	_____	sbasford 09/27/2005	lemery 10/06/2005	

Vers. Drafted Reviewed Typed Proofed Submitted Jacketed Required

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<END>

→ Not
Needed

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9/27
9275
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/?	csundber 06/27/2005 phurley						

Handwritten: 7255, pb

FE Sent For:

<END>

Sundberg, Christopher

From: Hogan, Rebecca
Sent: Friday, June 17, 2005 12:22 PM
To: Sundberg, Christopher
Subject: Pharmacy Examining Board draft request

Chris - I just wanted to give you a heads up that I am sending over a fax with some materials for your review. Can you take a peek as soon as you can and let me know if you can prepare a draft of the bill from the information I am sending?

Rebecca Hogan
Office of Senator Luther Olsen
608-266-0751



CTB

Luther S. Olsen
State Senator
14th District

FACSIMILE TRANSMITTAL SHEET

TO:	FROM:
Chris Sundberg	Senator Luther Olsen
COMPANY:	DATE:
Legislative Reference Bureau	06/17/2005
FAX NUMBER:	TOTAL NO. OF PAGES INCLUDING COVER:
608-264-6948	3
PHONE NUMBER:	SENDER'S REFERENCE NUMBER:
608-266-3561	
RE: DRAFT LEGISLATION	YOUR REFERENCE NUMBER:

☐ URGENT ☒ FOR REVIEW ☐ PLEASE COMMENT ☒ PLEASE REPLY ☐ PLEASE RECYCLE

NOTES/COMMENTS:

Chris - I was informed you would be the appropriate drafting attorney for the following information.

Can you please review these materials and have a bill drafted accordingly? Please call or e-mail to let me know if you need further information for the draft.

Sincerely,

Rebecca Hogan

(608) 266-0751

Jim Doyle
Governor

WISCONSIN DEPARTMENT OF
REGULATION & LICENSING



1400 E Washington Ave
PO Box 8935
Madison WI 53708-8935
Email: web@drl.state.wi.us
Voice: 608-266-2112
FAX: 608-267-0644
TTY: 608-267-2416

DATE: MAY 31, 2005

TO: Senator Luther Olsen

FROM: Susan L. Sutter, R.Ph.
Vice-Chairperson, Wisconsin Pharmacy Examining Board
Legislative Liaison

RE: Legislation for the emergency continuation of the practice of pharmacy

Thank you for your interest in possible sponsorship of legislation to address a public health issue for the pharmacy profession. Wis. Stat. Chapter 450, currently does not allow the Pharmacy Examining Board (PEB) to grant a variance to any of the provisions of Chapter 450 in the event of a homeland security-type emergency or a natural disaster that might affect public health, safety and welfare. Similarly, the administrative rule variance procedure is not applicable for certain rules which may require a variance resulting from such an emergency. Even where a variance to an administrative rule may be possible, the administrative process to seek such a variance cannot occur within a timeframe sufficient to meet an emergency which is occurring in real time and causing a real time risk of harm to the public. In the past, the Board chair or a Board designee has worked with the facts of the emergency situation and advised the pharmacist involved on what would be acceptable actions. The PEB believes the Board should be granted clear statutory authority to assist pharmacists and the public in these situations.

Examples of statutory provisions which may need a variance granted by the PEB are as follows:

1. Wis. Stat. §450.06-Pharmacists must normally dispense from a pharmacy only and a change of location first requires relicensure at the new location. In instances where a pharmacy or group of pharmacies in an area are damaged in an area following a homeland security or natural disaster-type emergency, a temporary location may need to be set up with modified dispensing protocols to meet public safety need. This type of variance is a fact-based variance evaluated on a case-by-case basis and structured within the professional discretion of the Board to retain security, accountability and non-adulteration of prescription drugs. Certain administrative rules, normally not subject to a variance would be implicated as well.

2. Wis. Stat. §450.035-Administration of drug products and devices. This type of variance may be needed in instances of mass infection or exposure to an agent in the population.

Included with this letter, is the proposed statutory language as drafted by our legal counsel, William Black. Feel free to contact me directly with any questions at 1-920-485-3400 or marshland@powerweb.net. On behalf of the Pharmacy Examining Board, thank you for your interest.

Emergency Continuation of the Practice of Pharmacy**PROPOSED STATUTORY LANGUAGE**

450.025 Emergency continuation of the practice of pharmacy. (1) In the event of a natural or man-made disaster or emergency and upon the request of a pharmacy, the board or its designee may grant a variance to a requirement of this chapter or a rule promulgated thereunder for the continuation of the practice of pharmacy by a licensed pharmacy upon conditions that the board or its designee determines are necessary to protect the public health, safety and welfare.

(2) Any variance granted under this section shall be for a stated term not to exceed 90 days unless extended by the board or its designee upon further request by the pharmacy.

fm 7/29

2005 BILL

627

1

general
AN ACT ...; *examining* relating to: powers of the pharmacy board during times of emergency
or disaster.

2

Analysis by the Legislative Reference Bureau

Under current law, the Pharmacy Examining Board (the board) enforces statutory requirements and promulgates rules to regulate the practice of pharmacy. Also under current law, the Governor has the power to declare a state of emergency for the state or any portion of the state if a public health emergency exists or if there is an emergency resulting from enemy action or a natural or man-made disaster exists. Unless the legislature passes a joint resolution to extend the duration of a state emergency, a state of emergency resulting from enemy action may not exceed 60 days and an emergency resulting from natural or man-made emergency disaster may not exceed 30 days. *is of*

Under this bill, the board may grant a variance to any statutory requirement or rule regarding the practice of pharmacy if there is a state of emergency for the state or any portion of the state, if a pharmacist requests the variance, and if the board determines that the variance is necessary to protect public health, safety, and welfare. The variance granted by the board may not exceed the duration of the state of emergency during which the variance was granted. *stat.*

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

BILL

SECTION 1

SECTION 1. 450.02 (3m) of the statutes is created to read:

450.02 **(3m)** (a) The board or its designee may grant a variance to a requirement of this chapter or to a rule promulgated by the board if all of the following are true:

1. A state of emergency exists for the state or a portion of the state, under s. 166.03.

2. A pharmacist has requested the variance.

3. The board or its designee determines that the variance is necessary to protect the public health, safety, or welfare.

(b) A variance granted under par. (a) may not exceed the duration of the state of emergency during which the variance was granted.

(END)

450.025 Emergency continuation of the practice of pharmacy. (1) In the event of a natural or man-made disaster or emergency and upon the request of a pharmacy, the board or its designee may grant a variance to a requirement of this chapter or a rule promulgated thereunder for the continuation of the practice of pharmacy by a licensed pharmacy upon conditions that the board or its designee determines are necessary to protect the public health, safety and welfare.

(2) Any variance granted under this section shall be for a stated term not to exceed 90 days unless extended by the board or its designee upon further request by the pharmacy.

Rationale

Wis. Stat. Chapter 450, currently does not allow the Pharmacy Examining Board to grant a variance to any of the provisions of Chapter 450 in the event of a Homeland Security type emergency or a natural disaster that might affect the public health, safety and welfare. Similarly, the administrative rule variance procedure is not applicable for certain rules which may require a variance resulting from such an emergency. Even where a variance to an administrative rule may be possible, the administrative process to seek such a variance cannot occur within a timeframe sufficient to meet an emergency which is occurring in real time and causing a real time risk of harm to the public.

The examples of statutory provisions which may need a variance granted by the board are as follows:

1. Wis. Stat. §450.035- Administration of drug products and devices

- For instances of mass infection or exposure to an agent in the population.

2. Wis. Stat. §450.06- Pharmacists must normally dispense from a pharmacy only and a change of location first requires relicensure at the new location.

- In instances where a pharmacy or group of pharmacies in an area are damaged in an area following a Homeland Security or natural disaster type emergency. Often, a temporary location needs to be set up with modified dispensing protocols to meet public safety need. This type of variance is a fact based variance evaluated on a case by case basis and structured within the professional discretion of the board to retain security, accountability and non adulteration of prescription drugs. Certain administrative rules, normally not subject to a variance would be implicated as well.

Hurley, Peggy

From: Smith, Heather
Sent: Tuesday, August 09, 2005 1:10 PM
To: Hurley, Peggy
Subject: LRB 3225/1

*remove all for a stated term
5.19.00 days unless extended*

Hi Peggy,

In regard to LRB 3225/1, the pharmacy people we're working with have brought up a concern regarding the language in the bill.

I'm attaching an email exchange they've had on the topic, but basically issue is that often the need arises for them to make alternative arrangements for a pharmacy that wouldn't be in situations where the governor has declared an emergency...like a fire in one building or the like. They're trying to get at those kinds of situations.

If you want to talk to the PEB attorney on this - it's Bill Black at 266-1790.

Let me know what your thoughts are on this.

Thank you,

Heather Smith
Chief of Staff
Senator Luther Olsen

----- Original Message -----

From: "Tom Engels" <tome@pswi.org>
Date: Tue, 9 Aug 2005 11:02:31 -0500

Heather,

A concern was raised about the bill draft. Below is a correspondence between Bill Black, PEB legal counsel and Sue Sutter. The event the PEB was intending to cover with this legislation is more localized. The draft states the PEB would have this authority if state of emergency was declared by the governor. However, if a fire occurs at a pharmacy an emergency declaration is not likely to given and the PEB would have no authority beyond what it already has. I would suggest you have the LRB drafting attorney contact Bill Black.

Thanks for your help Heather.

Tom

On Tue, 9 Aug 2005 10:32:11 -0500

"Black, William" <William.Black@drl.state.wi.us> wrote:

You are correct Sue. This does not meet the need or intent of the PEB for the statute. A "state of emergency" may or may not affect a particular pharmacies ability to dispense. Rather, a localized particular event not rising to the level for the declaration of a "state of emergency", is much more likely to occur. This latter event is what the PEB's intent is aimed

> at, as it would affect the ability of a pharmacy to dispense.

>

> -----Original Message-----

> From: Marshland Pharmacy [mailto:marshland@powerweb.net]
> Sent: Tuesday, August 09, 2005 10:25 AM
> To: Tom Engels; Black, William; mike.bettiga@shopko.com;
> bohlman@facstaff.wisc.edu; cbenning@columbia-stmarys.org
> Subject: Re: FW:Emergency relocation bill draft?

>
> Bill,
>
> Have they made this so the only time it could be used is when the
> state declares a "state of emergency"? If so, this really doesn't
> meet our needs. The more common reason is a fire or tornado damage
> that may not be significant enough for the Governor to declare a state
> of emergency but that the pharmacy is not able to function.
>
> What's your take on their language?
>
> Sue
>

2005 BILL

8-29-05

Regen

1

AN ACT *to create* 450.02 (3m) of the statutes; **relating to:** powers of the

2

pharmacy examining board during times of emergency or disaster.

Analysis by the Legislative Reference Bureau

Under current law, the Pharmacy Examining Board (board) enforces statutory requirements and promulgates rules to regulate the practice of pharmacy. Also under current law, the governor has the power to declare a state of emergency for the state or any portion of the state if a public health emergency exists or if there is an emergency resulting from enemy action or a natural or man-made disaster exists. Unless the legislature passes a joint resolution to extend the duration of a state of emergency, a state of emergency resulting from enemy action may not exceed 60 days and an emergency resulting from natural or man-made emergency disaster may not exceed 30 days.

Under this bill, the board may grant a variance to any statutory requirement or rule regarding the practice of pharmacy if there is a state of emergency for the state or any portion of the state if a pharmacist requests the variance, and if the board determines that the variance is necessary to protect public health, safety, and welfare. The variance granted by the board may not exceed the duration of the state of emergency during which the variance was granted.

it determines that there is an

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

90 days, unless the board decides that an extension is necessary

BILL

1 SECTION 1. 450.02 (3m) of the statutes is created to read:

2 450.02 (3m) (a) The board or its designee may grant a variance to a
3 requirement of this chapter or to a rule promulgated by the board if all of the
4 following are true:

5 1. A state of emergency exists for the state or a portion of the state, under s.

6 166.03. The board or its designee determines that a natural or
7 man-made disaster or emergency exists or has occurred.

8 2. A pharmacist has requested the variance.

9 3. The board or its designee determines that the variance is necessary to protect
10 the public health, safety, or welfare.

11 (b) A variance granted under par. (a) may not exceed the duration of the state
12 of emergency during which the variance was granted.

(END)

shall be for a stated term not to
exceed 90 days, except that the
board or its designee may
extend the variance upon request
by a pharmacist if it
determines that an extension
is necessary to protect the
public health, safety, or
welfare.

Northrop, Lori

From: Smith, Heather
Sent: Wednesday, October 05, 2005 4:12 PM
To: LRB.Legal
Subject: Draft review: LRB 05-3225/2 Topic: Pharmacy board emergency variance authority

It has been requested by <Smith, Heather> that the following draft be jacketed for the SENATE:

Draft review: LRB 05-3225/2 Topic: Pharmacy board emergency variance authority